Advanced Tools and Technologies for Cerebrospinal Fluid Shunts STTR

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The official link for this solicitation is: http://grants.nih.gov/grants/guide/pa-files/PA-09-205.html

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Description:

Hydrocephalus is caused by a heterogeneous group of diseases and disorders that can affect individuals of any age, from infants to the elderly. Cerebrospinal fluid (CSF) shunts have been successfully used to treat hydrocephalus for over 50 years and are the most common treatment option for this disorder. In a typical shunt system, a catheter is used to drain the fluid from the brain to a site in the body where it can be absorbed, such as a chamber of the heart or the peritoneal cavity. Flow rate and direction are regulated by a valve.

While CSF shunts are a clinically proven technology that have enhanced the quality of life for many individuals, shunt obstruction and malfunction continue to be an issue affecting a significant portion of the treated population. A NIH-sponsored workshop on Hydrocephalus held in 2005 (http://www.ninds.nih.gov/news_and_events/proceedings/Hydrocephalus_2005.htm) identified the challenges and opportunities associated with hydrocephalus research that could eventually lead to improvement in patient outcomes. As noted at the meeting, hydrocephalus treatment has not changed significantly since the creation of the CSF shunt. Although adjustable valves have improved the outcomes for some individuals, overdrainage and suboptimal shunt operation still occurs in many patients. Shunt obstruction and malfunction are the most common causes of shunt failure and occur in approximately one third of pediatric patients in the first year. Obstruction often occurs at the ventricular catheter tip and the shunt valve. Mechanical failure includes fracture of the tubing, disconnection of components, and shunt migration. In preterm newborn infants, shunts are placed to relieve post-hemorrhagic hydrocephalus and, due to the higher than normal CSF protein contents, shunt malfunction and obstruction occurs secondary to protein coagulation around the shunt tip.

Many children with CSF shunt systems have additional surgeries to modify or replace the CSF shunt device during their lifetimes because of these issues. Infection occurs in 8-10% of cases and is also a significant concern because of increased morbidity, high re-infection rates, and other severe complications. Overdrainage with consequent collapse of the ventricles can also cause serious neurologic dysfunction. In the elderly, the treatment of normal pressure hydrocephalus (NPH) by ventricular shunts can result in major neurologic improvement. However, as the ventricles decrease in size and the atrophic brain collapses away from the dura, bridging veins may rupture. Consequently subdural hematoma formation is a common, major serious adverse event in such patients that leads to significant loss of quality of life. Diagnosis of CSF shunt failure or suboptimal shunt operation can be difficult. Smptoms of CSF shunt failure usually affect cognition (abulia), gait and continence. These changes may be particularly difficult to ascribe to a specific cause in the elderly. Although imaging and pressure sensors exist, many outcomes are qualitative in nature and may require baseline information about the patient. Current diagnostics and assessment results may depend on the type of failure, the system type, and patient age. In addition, real-time diagnostic tools for the outpatient or home setting do not exist. New innovations that incorporate the tremendous activities in material science, micromechanical systems, biomaterials, nanotechnology and other new bioengineering innovations could improve treatment of hydrocephalus. The ideal system would include a feedback design to regulate the ventricular pressure and/or volume.

Syringomyelia, formation of an expanding syrinx (fluid-filled cyst) within the spinal cord due to obstruction of normal CSF flow, is related to hydrocephalus or spinal cord injury. Syringoperitoneal shunts to drain the syrinx are widely used, and subject to the same blockage, infection and other complications noted above.

The purpose of this initiative is to stimulate the development of: 1) Monitoring and diagnostic tools for determining and/or controlling CSF shunt function and 2) improving CSF shunt design and materials to decrease shunt failure rates. The tools and technologies developed under this program will improve shunt design, and the diagnosis of shunt failure, leading to an improvement in the quality of life for hydrocephalus patients with CSF shunts. Diagnostic and assessment technologies developed through this initiative would improve monitoring and diagnosis of shunt failure in both the home and the clinic, allowing patients to identify issues before significant side-effects occur. Also included are technologies that will improve patient outcomes by reducing the CSF shunt failure rates and improving shunt operation. Different hydrocephalus patient groups may also have different needs, for example younger patients need systems that take into consideration patient growth and require devices with long lifetimes. Projects with the potential for near term clinical impact are strongly encouraged, but exciting and novel longer-term proposals are permissible. Diagnostic tools for hydrocephalus to determine if shunt treatment is necessary and diagnosis methods for general CSF infection are not appropriate for this initiative.

The following research topics would be appropriate for Phase I or Phase II projects under this initiative. This list is not meant to be all-inclusive:

Innovative CSF Shunts:

- Shunt components that reduce obstruction at the ventricular catheter tip and/or shunt valve
- Shunt systems that decrease the risk of overdrainage, particularly in pediatric populations or the elderly who are at risk for secondary subdural hematoma.
- Unique shunt systems designed to significantly reduce the chance of mechanical failure or suboptimal shunt operation
- Shunt systems that minimize or eliminate bacterial biofilm and thrombus formation.
- Shunt systems that are compatible with diagnostic imaging technology

Diagnostics and Monitoring:

- Diagnostic tools for use in a hospital or outpatient setting that work in real-time to quantitatively determine shunt function.
- Monitoring and diagnostic tools for the home setting to detect shunt problems at the early stage (i.e. right before or immediately after failure)
- External monitoring tools or implantable sensors to detect suboptimal shunt operation, such as overdrainage, through the measurement of CSF dynamics
- Feedback systems in which sensors monitor and then vary shunt operation to maintain specific values for ventricular volume and pressure.

Novel Materials:

- Materials for shunt system components that decrease bacterial adhesion or have short-term antibiotic properties
- Materials that decreased cellular occlusion and/or host reactions over the life of the shunt system
- Materials with longer implant life that resist mechanical failure